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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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09/056,806      04/08/98      VERMEULEN

A      I/97272

EXAMINER

HM12/0130

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TURNER, S

ART UNIT

PAPER NUMBER

1647

DATE MAILED:

01/30/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.

09/056,806

Applicant(s)

Vermeulen

Examiner

Sharon L. Turner, Ph.D.

Group Art Unit

1647



☒ Responsive to communication(s) filed on 5-9-00

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claim

☒ Claim(s) 1-15, 18, 19, and 21-32 is/are pending in the applicat

Of the above, claim(s) 6-11, 18, 21-26, 29, and 31 is/are withdrawn from consideration

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 1-5, 12-15, 19, 27, 28, 30, and 32 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☒ Claims 1-15, 18, 19, and 21-32 are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been

☒ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 2

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

Art Unit: 1647

### **Response to Amendment**

1. The Art Unit of U.S. Patent application SN 09/056,806 has changed. In order to expedite the correlation of papers with the application please direct all future correspondence to Examiner Turner, Technology Center 1600, Art Unit 1647.
2. The amendment filed 5-9-00 has been entered into the record and has been fully considered. Claims 1-15, 18-19, and 21-32 are pending.
3. Applicant's affirmation of the election of Group I, claims 1-5, 12-15, 19, 27, 28, 30 and 32 in Paper No. 4 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
4. Claims 6-11, 18, 21-26, 29 and 31 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 4. The examiner notes that claim 13 remains in part drawn to nonelected claim 11.
5. As a result of applicants amendment, all rejections not reiterated herein have been withdrawn by the examiner.
6. In the response of 9-27-99 applicants stated at p. 3, lines 20-23 of the remarks that, "This terminology (this referring "variants") has been deleted from the claims under consideration, it being understood that the claims as they stand include natural variants" The examiner stated in the response that the specification and claims did not support variants or natural variants as

Art Unit: 1647

asserted by applicants. To clarify, the examiner intended the statement to indicate that the interpretation of the claims as they stood did not include natural variants as asserted by applicants at p. 3, lines 20-23 of the remarks. The statement was interpreted by applicant's representative to imply a new matter rejection. Applicants have pointed to p. 5-6 to show written description support for such language in the specification. The examiner clarifies that applicants provide written description support for variants and natural variants as set forth at p. 5-6 of the specification and that such language is not new matter.

***Claim Objections***

7. Claim 13 is objected to because of the following informalities: Claim 13 remains drawn in part to nonelected claim 11. Appropriate correction is required.

**Rejections Maintained**

8. Claims 1-5, 12-15, 19, 27, 28, 30 and 32 stand rejected under 35 U.S.C. 102(b) as being anticipated by EP0382531, Gurnett, 16.08.90.

Applicants argue that the claimed invention is directed to a composition free of whole eimeria parasites which comprise one or more proteins or fragments thereof wherein the proteins are present in the hydrophilic phase of a Triton X-114 extract of Eimeria sporozoites and that therefore the Gurnett reference is not anticipatory.

Applicants arguments filed 5-9-00 have been fully considered but are not persuasive because the Gurnett reference teaches that when the lysates are treated after phase separation the hydrophobic glycolipid linked proteins are found in the detergent phase, however, when lipase is

Art Unit: 1647

added prior to phase separation, the proteins are found in the aqueous (hydrophilic) phase, see in particular Example 5, p. 9, lines 52-53 and Example 6, p. 10, lines 24-27. Thus, the molecular weight determination of the four major glycolipid linked proteins from *E. tenella* sporozoites prepared via such methods as demonstrated in Examples 5 and 6 reveals that the proteins which may be isolated either in the hydrophilic fraction (when lipase is added prior to phase separation) or the hydrophobic fraction (when lipase is added after phase separation) exhibit the desired molecular weight characteristics of applicants claims. As the evidence shows that the disclosed proteins may be isolated from the hydrophilic phase of a triton X-114 detergent extraction, the disclosed peptides, compositions and vaccines as claimed appear to be anticipated by the prior art.

### **New Rejections Necessitated by Amendment**

#### ***Claim Rejections - 35 USC § 112***

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 14 and 28 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection. Claim 14 has been amended from "Quil A" to recite "a saponin." The claim amendment is deemed to introduce new matter

Art Unit: 1647

into the specification because there does not appear to be written description support for the broad genus of saponins encompassed by the claims. In particular, the examiner notes that a search of the registry file indicates 1130 saponins known in the literature as exemplified by for example by assamsaponin H, G and F, see in particular registry numbers 316157-17-2, 316157-16-1 and 316157-15-0, whereas a search of the registry file indicates Quil-A limited to registry numbers 227621-56-9, 227621-94-5 and 66594-14-7, exemplified by Sorbitan, tri-(9Z)-9-octadecenoate, mixt. with (3.beta.)-cholest-5-en-3-ol, (6E, 10E, 14E, 18E)-2,6,10,15,19,23-hexamethyl-2,6,10,14,18,22-tetracosahexaene, Quil-A and sorbitan mono-(9Z)-octadecenoate poly (oxy-1,2-ethanediyl)derivatives (9CI). Thus, the genus of molecules represented by saponins appears to be a broader in scope than the species of Quil A saponins supported by the specification at for example p. 19, line 18 as pointed to by applicants. Thus, the broad recitation of "a saponin" appears to introduce new matter.

#### **Status of Claims**

11. No claims are allowed.

#### **Conclusion**

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire **THREE MONTHS** from the date of this action. In the event a first response is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after

Art Unit: 1647


the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

13. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon L. Turner, Ph.D. whose telephone number is (703) 308-0056. The examiner can normally be reached on Monday-Friday from 8:00 AM to 4:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached at (703) 308-4623.

Sharon L. Turner, Ph.D.  
January 29, 2001

  
GARY L. KUNZ  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600